DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 20, 2014

Life Spine, Incorporated
Mr. Randy Lewis
General Manager
2401 West Hassell Road, Suite 1535
Hoffman Estates, Illinois 60169

Re: K140236
Trade/Device Name: Aileron Interspinous Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: September 24, 2014
Received: September 25, 2014

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140236

Device Name
Aileron Interspinous Fixation System

Indications for Use *(Describe)*
Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The Aileron Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous processes in skeletally mature patients for the purpose of achieving, in conjunction with autogenous bone graft, single level supplemental fusion in the following conditions: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies), (2) trauma (i.e., fracture or dislocation), (3) spinal tumor, (4) spondylolisthesis. The Aileron Interspinous Fixation System is not intended for stand-alone use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Aileron Interspinous Fixation System

Submitted By: Life Spine, Inc.
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Fax: 847-884-6118

510(k) Contact: Randy Lewis
Life Spine
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Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: September 24th, 2014

Trade Name: Aileron Interspinous Fixation System

Common Name: Spinal interlaminal fixation orthosis

Classification: PEK, 888.3050, Class II, Spinal interlaminal fixation orthosis

Predicate Device: Primary Predicate: Aileron Interspinous Fixation System (K113157)

Additional Predicates: Life Spine Interspinous Fixation System (K100407), Lanx Spinal Fixation System (K090252)

Device Description:

The Aileron Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). Implants are manufactured from titanium alloy per ASTM F136 and are available in a range of sizes to suit the individual pathology and anatomical conditions of the patient. The purpose of this submission is to clear device modifications to the Aileron Interspinous Fixation System.

Intended Use of the Device:

Internal fixation implants are load-sharing devices intended to stabilize and maintain alignment until normal healing occurs. Implants are not intended to replace normal body structures or bear the weight of the body in the presence of incomplete bone healing.

The Aileron Interspinous Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous processes in skeletally mature patients for the purpose of achieving, in conjunction with autogenous bone graft, single level supplemental fusion in the following conditions: (1) degenerative disc disease (is defined as back pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies), (2) trauma (i.e., fracture or dislocation), (3) spinal tumor, (4) spondylolisthesis. The Aileron Interspinous Fixation System is not intended for stand-alone use.

Technological Characteristics:

The Aileron Interspinous Fixation System is substantially equivalent to the predicate systems in terms of design, materials, and indications for use.

Material:

The Aileron Interspinous Fixation System is 6AL-4V-ELI titanium manufactured according to ASTM F136. The device is comprised of a variety of non-sterile titanium, single use components.

Performance Data:

Static and dynamic compression and torsion testing in accordance with a modified ASTM F1717 setup, in addition to Spike Pull-off and Static Axial Grip testing, was presented to demonstrate substantial equivalency.

Conclusion:

The information presented demonstrates the substantial equivalency of the Aileron Interspinous Fixation System.